

# SUMMARY

## mHealth - Smart Media and Health: Applications Benefiting Life in Space and on Earth

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### Executive Summary

The theme of the third NASA Human Health and Performance Center (NHHPC) workshop for members was mHealth - Smart Media and Health: Applications Benefiting Life in Space and on Earth. The focus of the event was on mobile health applications benefitting not only global and space health issues but also technologies for consumer-driven healthcare mobile access, democratizing health diagnostics, and a variety of smart phone applications (see [Appendix A](#)). The workshop included keynote speakers and a panel discussion highlighting the need for mobile access technologies for both Earth and space applications (see [Appendix B](#)). The event continued with members participating in multiple breakout sessions in key areas of health- and mobile health-related topics. Members were encouraged to openly discuss technology and policy as they related to the topics of interest. The workshop concluded with a dynamic and interactive keynote address from Todd Park, US Chief Technology Officer (see [Appendix D](#)).

The breakout sessions were intended to create connections and start conversations across the different NHHPC member organizations and facilitate development of collaborative projects or challenges around health and mobile applications. Mozilla's MoPad was used to capture the summaries of these breakout sessions. The topics for the breakout sessions included:

- Health Care Data Access/Monitoring
- Health Technologies for Smart Phones
- 21<sup>st</sup> Century mHealth Communications for Social Good
- Smart Phone Apps
- Environmental Health Technologies
- FDA Guidelines on Mobile Health

Summaries (see [Appendix C](#)) of each topic include discussion points and any feedback given by the NHHPC members and participants who attended the break-out sessions.

A survey was conducted to assess member expectations and solicit feedback regarding the most (and least) valuable aspects of the event. Of the 70 members who attended the event, 54% of the members who responded represented a government agency, 30% were from industry, 8%

were from academia, and 8% were from non-profit organizations. Member feedback will be taken into account and used in future NHHPC event planning.

Overall, the mHealth workshop was considered a success. The 70 members who attended represented 39 different NHHPC member organizations (see [Appendix E](#)) with an additional 20-30 social media enthusiasts, totaling 47 participating organizations. Additionally, participants were invited to interactively participate on Twitter using #NASAhealth, which resulted in over 640 tweets from the day's event and discussions and comments made after the event. Some of the comments included:

- "mHealth: Smart Media and Health" seems to be a far more diverse event than I normally attend"
- "[#NASAhealth](#) is a great way to close out [#DCInnovation](#) week!"
- "[#NASAhealth @NASAHumanHealth](#) also works to develop wearable data collection devices that has space-earth benefits for flight AND home health"
- "Anyone else completely astounded by all the [#mHealth](#) innovations being shared at [#NASAhealth](#)?"

The feedback received from this and previous NHHPC workshop events indicates that the most valuable aspects were networking with other NHHPC members, especially the opportunity to network with NASA, and share ideas. Specifically for this workshop, it was noted that the keynotes, panel, and breakout discussions were extremely valuable and informative. Additionally, 36% of survey responders stated they would commit to a project with the NHHPC, 55% responded "maybe," and only 9% responded "no."

## Conclusions and Recommendations

This report and all presentation materials are available on the [NHHPC website](#). The specific recommendations identified from this workshop are as follows:

### General Survey/Feedback Results

1. Continue to capture notes and feedback from the NHHPC events and post to either the NHHPC website or NHHPC wiki, based on sensitivity of the material.
2. Move the evening reception to the night before the workshop for more participation and greater turnout.
3. Provide more structure to the breakout session facilitators – the breakout sessions differed on structure resulting in some being more interactive than others.
4. Consider adding more panels and/or short presentations.
5. Continue to improve communication of upcoming workshops and options for NASA personnel to participate if unable to travel.
6. Continue to improve communication regarding connections made for NASA to subject matter experts within the Directorate who were unable to attend.

## Appendix A – NHHPC Workshop Agenda



### **mHealth: Smart Media and Health Applications Benefiting Life in Space and on Earth**

Workshop for NASA Human Health and Performance Center Members  
**Kaiser Permanente Center for Total Health**  
700 Second St. NE, near Union Station  
Washington, DC  
June 7, 2012 (7:30 am – 5:10 pm ET)

#### **Networking Reception**

Sponsored by **wyle**  
Immediately following the workshop (5:10 – 7:00 pm ET)

## **Agenda**

Presenter	Topic	Time
<b>Registration</b>		7:30am
Jeff Davis (NASA JSC), Elizabeth Richard (Wyle), Aman Bhandari (HHS), Danielle Cass (Kaiser Permanente)	Welcome	8:00 am
<b>FEATURED KEYNOTE</b>		
Philip Fasano (Kaiser Permanente)	Consumer-driven Health Care: Mobile access for Mobile Patients	8:10 am

Jeff Davis (NASA JSC)	NASA Developments in Mobile Health	8:35 am
<b>PANEL</b>		
Moderator: Jeff Davis (NASA JSC) Panel Members: Ramesh Raskar (NETRA, MIT Media Lab) William Riley (NIH/NHLBI) Todd Schlegel (NASA JSC) Bakul Patel (FDA) Jeff Sutton (NSBRI)	mHealth: Earth and Space Applications	9:00 am
<b>Break</b>		<b>10:30 am</b>
<b>PRESENTATIONS</b>		
Scott Snyder (Mobiquity, Inc.)	Unleashing the Power of Mobile Innovation in Healthcare	10:45 am
Nate Gross (Rock Health)	Innovating in Digital Health	11:15 am
<b>Lunch</b>		<b>11:45 am</b>
<b>BREAKOUT SESSIONS</b>		
Jeff Davis (NASA JSC)	Charge for the Breakout Sessions:	1:15 pm
All	<ul style="list-style-type: none"> <li>Health Care Data Access/Monitoring (Robert Jarrin – Qualcomm Inc)</li> <li>Health Technologies for Smart Phones (Audie Atienza – NIH; David Haddad – Open mHealth)</li> <li>21<sup>st</sup> Century mHealth Communications for Social Good (Scott Ratzan – J&amp;J; Michael Weinberger – J&amp;J; Todd Schlegel – NASA JSC; Carissa Vidlak – Wyle)</li> </ul>	1:20 pm
<b>Break</b>		<b>2:45 pm</b>
All	<ul style="list-style-type: none"> <li>Smart Phone Apps (Mohit Kaushal – West Wireless Health Institute; Felasfa Wodajo – iMedicalApps.com)</li> <li>Environmental Health Technologies (e.g. air) (David Balshaw – NIH/NIEHS)</li> <li>FDA Guidelines on Mobile Health (Megan Moynahan – FDA)</li> </ul>	3:00 pm
<b>FEATURED KEYNOTE</b>		
Todd Park (US CTO)	Innovation and Entrepreneurship in Healthcare	4:30 pm

Jeff Davis (NASA JSC)	Closing Remarks	5:00 pm
NETWORKING OPPORTUNITY		
Tom Anderson (Wyle)	Welcome	5:10 pm

## Appendix B – NHHPC Panel Q&A

### Panel (Q&A)

The NHHPC Panelists included Ramesh Raskar with MIT Media Lab and NETRA, William Riley from NIH/NHLBI, Dr. Todd Schlegel with NASA-JSC, Jeff Sutton from NSBRI, and Bakul Patel of the FDA. The panel was moderated by the NHHPC Director, Dr. Jeffrey Davis. Below are a few of the questions and answers that were captured during the panel discussion.

Q: Can you give details on sex and gender/human factors as they relate to FDA released policies?

- More difficult to collect ECG in females than in males

Q: What are the tradeoffs in remote places to feed funding to remote locations?

- [LAUNCH](#) got NETRA thinking about this and there are new models and more collaborators needed
- Issue is upfront costs (ex: eye care, change from per test to per device)
- We want to reach millions of people

Q: Do we put a cloud out for ISS/MPCV data to be computed? What about privacy versus storage/devices?

- Privacy/security and human factors are issues; India is not afraid to post on Facebook but in US everyone is afraid to post their status; US is risk averse; technically it depends on more data, what kind of data, how closely does the data relate to a person and how is the data used
- Need standards on hardware as well, we are hoping standards evolve over time
- Contemplated privacy for a while; the data is viewed only while logged on so nothing left on device regardless of the device; standards using national standards to exchange medical records; privacy and security a very serious issue to tackle; social media is self-induced so no HIPPA violation
- Low tech way (paper) can be lost as well, need to recognize we must always be careful with data but technology actually makes the data more secure

Q: Scalability – is there an app for monitoring/education?

- Need to review research throughout development process
- Leverage technology more to automate monitoring (RCT)
- Think we can speed up the process quite a bit
- Tendency to form a diagnostic device and need to focus on evaluation/analysis tools/devices

Q: If people don't understand how to use them, how can smart phones, voice recognition, etc be used for apps in developing countries?

- About human experience; user interface; true fusion of user interfaces
- Developing countries – there is an assumption of a local health physician

Q: FDA approval of a device - how does the FDA juggle complexity and allow end user to move forward?

- Operating system is not controlled by the manufacturer, the manufacturer just supplies the pieces; the challenge is for the FDA to approve the operating system when it is already in a device; in the past, component lots were controlled by specs and these components would not even be made half the time. The focus needs to be back on the risk management of mobile health; some companies go on iOS for lots of reasons and then come to FDA; lots of ways to approach FDA; FDA is the expert company to control technology to reduce risk
- Lots of work ahead for FDA for hardware makers. Could a new paradigm be coming? Maybe crowdsourcing experts to provide feedback to FDA

Q: Are there core use cases available to look at to find patterns/trends and then assess how mobile it needs to be?

- Lots of cases with ECG; back end software or analytics
- Yes lots of cases and probably experts have the same
- Don't have standard list of core use cases, great suggestion and would be great to pull them and create a new project
- Major trend to moral trend, not just data trend
- Collect on healthy and sick populations so database will be huge

Q: Is there a generation gap for using this technology?

- Any demographic can use these technologies
- Median age of Rock Health is 45
- Now doctors are faster adopters of tablets



## Appendix C – NHHPC Workshop Breakout Session Summaries

### Breakout Session: Health Care Data Access and Monitoring

**Facilitator:** Robert Jarrin, Senior Director of Government Affairs for [Qualcomm Incorporated](#)

Summary: 14 participants

The discussion started with different members presenting some of their health care data access and monitoring issues and ideas. Specific examples that were mentioned were as follows:

- RxMind Me developer shared that he developed an app to help him keep track of taking his medication. He could keep track of everything and even used it when his dog was ill and he had to manage the 14 medications the dog was given to take.
- Wyle highlighted the data dilemma in the Space Life Sciences Directorate at NASA-JSC and the challenge of getting access to all the data sets.
- NIH discussed research and evaluation and the need to collect data from clinical trials. What is important to them is getting comprehensive data to do the analysis.
- A health data codathon had taken place during DC Health Data and Innovation Week that used data to prevent obesity was shared. It started in California where every school was given a score using BMI data and other factors. The result was a “schoolfit” score.
- Rock Health has a culture of using the data that's collected. One big issue is getting quality data from one place.
- Doximity has worked to get quality of data up to date. Todd Park has been a big influencer of this and it has been good for everyone. Refresh cycles for data are now updated.

There were a number of questions that were asked about health data access including:

There are websites by doctors for doctors where mobile apps and software are reviewed, but how good is this information? When data is shared, how do we ensure that it's accurate since we are pulling from different equipment? Moving forward, how does this get standardized? How do we find the balance between privacy and transparency?

Additionally, the group mentioned health data access needs. Some specific areas were as follows:

- NASA mentioned needs in supplying medical equipment for space station. The hardware supplies work with the doctors and researchers to determine what kind of data is really needed and how best to acquire that data. Parallels were drawn between the aerospace and auto industries in that both have harsh environments. In terms of monitoring, it was suggested that building in the algorithm in the sensors that gives you the real-time monitoring required could be a solution. Sensors in a car make a 1/100th of a second decision.

- FDA needs validation data. The FDA is in charge of minimizing the risk of patient harm. FDA is a 3rd party auditor in many cases confirming that certain criteria is met and that whatever is being used really works safely, effectively, and is quality. FDA interested in hearing more and more from the patients themselves. Anecdotes need to turn into data that FDA can use.
- The ability to tap into information and see what these companies are doing with the data.

### **Breakout Session: Health Technologies for Smart Phones**

**Facilitators:** Audie Atienza, Behavioral Scientist at the National Institutes of Health ([NIH](#)) and David Haddad, Program Manager for [Open mHealth](#)

#### **Summary:**

This breakout session had three discussions around up-and-coming health technologies for smart phones. At the beginning of the discussion a few examples mentioned were advances in technology such as wearable sensors that monitor the environment or one's diet that are moving from outside the body to inside the body as technology develops. It was acknowledged that technology is being driven forward rapidly, and sometimes without careful thought for what is really needed.

The first discussion was centered on mobile apps for people who fly. How do you prepare individuals for flight? Solutions were discussed as follows:

- Provide a check list app so they don't forget their meds or provide information on how to get meds or care at their destination.
- Airlines currently send a reminder about your flight. Add a button where you can input your personal info and it will give you a list of potential medical issues during flight, thrombosis, etc. This could be animated for illustrated examples. Drugs interactions and possible side effects could also be incorporated with GPS mapping of pharmacies.
- Include a button on the check-in screen of your airline to click if you have a potential medical condition that is risky for flight so you can be observed for issues.
- Vaccinations are also important for traveling, especially overseas.

**Idea during the discussion:** perhaps a public-private partnership could be used to build in research when developing the app rather than at the end. Create a Data Safety Board or something along those lines before investing money. How do you work together and have oversight to verify that the person interpreting the information is doing so correctly?

- Need a matchmaker or a group that has the ability to tailor and facilitate partnerships and bring them together around common interest.
- What are the risks and how can those risks be vetted?
- How do we address personalized risk based on personal environment?

- How do you bring together a physiologic personal item and a sensor within your smart phone that picks up the environmental data?
- How do you reach the customers? Someone comes up with a really cool, incredible idea and there is not a way to get it out there and funded. Maybe not true science, but clever engineering.
- Why are no mHealth apps in the most sold/used apps on iTunes? Department of Defense is more receptive to trying “out of the box” items than other agencies-- including VA. Profit for many of the apps developed for third world countries is not the driving issue.

The next discussion centered on telemedicine applications and needs. The first part of the discussion focused on space applications – the need for a virtual doctor in space. Some needs that were outlined were as follows:

- The ability to do body scans for a diagnosis from the ground. This would lead to a treatment plan and would be non-invasive diagnostics. Diagnoses as good as or better than a board-certified surgeon.
- The ability to go beyond lower Earth orbit (LEO) using telemedicine. Large delay time when going to Mars – how do you minimize?
- Need to make the medical download autonomous. Is this an issue that can be dealt with in a remote location with what is on board? No physician is always available, so a smart system will be needed. Would something like Watson MD or Isabel software be a solution?

Finally, an app for Asthma was discussed as an example. It was based on an Asthma study which met the NIH criteria for management.

- Question: How do you create a business model showing how it will be paid for?
- Answer: Short development time to get a pilot up and running. A champion or advocate for the app is also needed. One can also follow a self insured model where the employer gives employees a set dollar amount for them to use on a smart phone app.

### **Breakout Session: 21st Century mHealth Communications for Social Good**

**Facilitators:** Dr. Scott Ratzan, Vice President, Global Health, [Johnson & Johnson](#); Michael Weinberger, Director, Marketplace Innovation, [Johnson & Johnson](#); Dr. Todd Schlegel, Senior Scientist and Medical Officer at [NASA's Johnson Space Center](#); Carissa Vidlak, Communications & Strategy Coordinator for [Wyle](#)

Summary: 15 participants

The breakout session started with a short presentation by Michael Weinberger and Scott Ratzan discussing their prototype mobile app called ScoreMyHealth. The app is based on research by Scott Ratzan on health literacy efforts. Michael's role as the innovation person is to take Scott's concepts and make them into something real and establish partnerships. The app

is to address the fact that so many people don't know if they are healthy or not, so this is intended to help people quickly get a grasp on the status of their health. The tool is different than a health risk assessment in that it is intended to give you a read on a select few health factors. This is a public health initiative and is currently a public prototype, to be officially launched in 2013 in different parts of the world. Johnson & Johnson's sustainability goal is to have 100 programs in 25 countries and getting people to know their basic numbers.

Highlights of this app were as follows:

- The goal is to integrate primary and secondary prevention strategies, to give the individual the knowledge and help to make important decisions regarding their health
- The intent is to take the tool to developing countries, but will need to change the questions to address specific needs of those areas
- After the tool gives you your number, you can go back and do a what-if scenario and change factors to see how you can improve--this represents the gamification of health care, providing the right behavior incentives at the end of this can make it work
- The challenge is how do you make this stick and using what vehicles?

Some additions or other areas that should be considered for J&J's app were suggested by the participants as follows:

- Incorporating diet or sleep questions
- Enable changing answers to do "what if" assessment right there on page where the question is asked rather than at the end
- Incorporating a share button to link to health records--health is private, exercise is individual, but wellness is social--can share score and start discussions with a larger audience
- Addressing insight and judgment – this is usually the last thing on a psychiatric assessment
- Feed forward and feedback loops to increase your understanding of health processes and bring in new information (health and social information) through social media
- Mint.com is a model that aggregates data so users can compare their budget with others, this kind of competition could be good in this tool as well
- Allergies should also be taken into consideration and the fact that some criteria may include dietary things and best practices that some people can't do--e.g., food allergies
- What are the metrics that they are trying to measure against, if from population what is motivation to have individuals to use, how useful is this really?

Dr. Todd Schlegel then gave a short presentation on the 12-lead ECG technology he discussed during the panel but focused this discussion on the social good benefits. His highlights included the need for easy, lower cost 12-lead electronics, the movement to associate electronics with low cost devices, the ability to build open source software for data collections, and the ability to pair the overall system with other NASA inventions. He also highlighted the need to use a single device for many patients. The participants then discussed their feedback as follows:

- Why choose open source software and who is going to certify or validate it? Can it not also be given away for free? Todd suggested in the end we do both: have an official version but also an open sourced version
- Liability concerns were raised on using this kind of technology. The comment was made that the American liability culture concern is not universal--liability can impact a doctor's decisions in the U.S. but that may not be the case in other countries
- Another participant brought up that there is a really great example of a wearable vest with sensor developed in Italy. At end of the testing period, the people wearing it did not want to give it back.
- A participant cautioned that some sensors for this kind of application do not have a medical model to tell non-cardiologist users what to do with continuous real-time data.

### **Breakout Session: Smart Phone Apps**

**Facilitators:** Mohit Kaushal, Executive Vice President of Business Development and Chief Strategy Officer, [West Wireless Health Institute](#) and Felasfa Wodajo, MD, Senior Editor, [iMedicalApps.com](#)

Summary:

In this breakout session, different smart phones applications were discussed along with a discussion on how to overcome the limitations.

Smart Phone App ideas:

- Developing an app for asthma. This app could cover environmental as well as behavioral issues. Mobile tools for tracking medicine and the environment need a business model to be able to fund the startup activity. This could help reduce costs relating to hospital and ER visits as well as costs associated with managing the patient's health. It could also be used as an incentive to create interest in lifestyle analysis and engagement in recording that kind of information. What is available currently is largely printed materials that are not well utilized.
- Mobile apps aimed to help psychiatry in Africa for the nomadic populations. How can we use technology to provide assessment and service to a nomadic population where HIV is prevalent?

Smart Phone App limitations/questions:

- How do you shift care from grants to being paid for by medical apps that do not have to see patients?
- How do you set up clinical trials without measurable data? One possible solution could be setting up a registry to show an app is effective and useful to patients.

- Health professionals want to know what apps are reliable and certifiable for health use. How could this be monitored? Apps are free and may require professional backing for consumers to feel comfortable using them.
- Health insurance companies should consider counting medical apps toward health care deductibles or insurance premiums.
- Right now there is a huge gap between paid for and free apps. Too early to decide what a game changing app might be. The pace of innovation is moving faster than we can track.

#### Social aspects of Smart Phone Apps:

- If people know something is going to work, it produces action on a national level. In Africa, you can reduce HIV infection in half by circumcision. It was introduced, but customs and religious beliefs were an initial barrier. After those barriers were overcome, it became so popular local clinics started to offer it for free. 70% had the surgery and it began to catch on in other areas. This was not done through the government, but word of mouth, people seeing the results, and socialization.
- iPhone Health World. You can't underestimate the social aspect of something like this. There will not be 100% buy in, but it's not necessary if you are able to get 50-60% of the population healthy.
- Is there a digital divide? Who is using the internet vs. using a cell phone? How do we empower women to have the same access? Why have we gone away from conversations to text messaging? What happened to the social aspect of sharing? These issues need to be taken into account and worked on in parallel.
- Relationships drive behavior change on some level since it is a developmental process. The hope would be some national access for all is created to move the agenda forward.
- Take lessons from industries like tobacco. Behavioral change has been a huge problem. Incentive didn't happen through cute messages. Strong incentive through the health care system, cultural change and peer pressure which resulted in social change.

#### Access to Smart Phone apps:

- In the developing world text messaging programs are more available than apps. The technology may have to be customized to the environment that will support them. Solving health problems is not about the technology. 12,000 Health on iTunes.
- Mental health seems to be one of the biggest areas unavailable after you leave large cities. There is supporting data demonstrating mental health care is superior face to face. Women like the face to face interface. More women are seen in person than men. Skype is being used for diabetic education – it has a more personal feel.

#### What makes a successful app?

- Gamefication to health apps could help engage the population and aid in behavior modification. Socially shaming them into the activity? Can't sell doctors on a social network – it must save them time.
- How do you get people to do better for themselves? Prizes are not motivators. Social group might motivate some folks that want to take control of their own health.
- The user interface is a big issue. Health care has traditionally been designed to make it easy for doctors. Things need to be simplified. Whatever you use must fit into the flow of your daily life. How do you get things to fit? We need the ability to correlate different data sets. If the app does not store your data somewhere else, people won't go back to it.
- Example of successful apps:
  - Healthragious
  - TurboTax. Imports your data from different streams, immediate feedback as you go along.
  - Facebook is a life wall. 90% of data in the world has been created in the last 2 years. Need tools for the medical professional community to make sense of our life. Consumer will start driving the decisions due to costs.

### **Breakout Session: Environmental Health Technologies**

**Facilitator:** David Balshaw, Ph.D., Emerging Technologies, National Institute of Health Sciences/[NIEHS](#)

Summary: 11 participants

The breakout session began with an overview of the NIEHS and how they address environmental health and how linkages between health and the environment can be improved.

David Balshaw's overview hit on the following key points:

- The NIEHS addresses environmental health based on how the environment impacts your health. The NIEHS is trying to develop sensor technologies to measure environmental factors and integrate it with lifestyle data and with molecular and physiological responses.
- What can be done in the mobile health arena to improve the linkages between environment and health to improve overall health?

The group then divided up into small groups of people to think of topics and ideas that were brought back to the entire group for discussion:

First discussion: Data Interoperability (brought up by NASA)

- Two main questions: 1. Why does this exist? Is it from a lack of money and/or lack of interest, especially with existing systems? 2. How do you link data manually, and then figure out how to automate?
- David Balshaw suggested looking at "My Air, My Health," which is an effort put together by the EPA & Health and Human Services, to get started. This effort is aimed at integrating exposure assessment data with epidemiological data. This can be used to empower communities to do something positive to impact health.
- Other suggestions/key issues:
  - The use of different vocabularies and provenance of data--from where did it come and how was it validated? Form and structure of data.
    - This can be addressed by forming an intermediate layer rather than strictly making it interoperable
  - Data we think is structured is not and is not useful to many
  - Start with challenges as opposed to users. Work with the tasks, get feedback from the community as well as the market.

Second discussion: Development of Sensor Technologies (NASA, Wyle, Futron, PepsiCo)

This discussion focused on environmental analysis using apps. A particular interest in water quality for users (in space and on Earth) was discussed – mainly being able to determine whether or not drinking water is of good quality.

- How do you make a suitable app?
- Start with an app that allows people to download quality of water wherever they are located. To start there wouldn't be immediate feedback, but data all over the world could be pooled over time and then hot spots could be correlated to e.g., obesity due to estrogen in water, or higher incidences of cancer and provide a starting point for developing a higher quality app. This strategy could also be used for air quality monitoring and for sound monitoring (hearing protection needed). The app could potentially become a multifunctional environmental monitoring app--for noise, water, air, humidity, etc.
- Another suggestion: microbial monitoring
- Do these technologies already exist?
  - It may exist - we need to do tech search to verify.
- A story was referenced regarding twins: a journalist did research on why one brother was impacted by mystery illnesses but not the other. They then did a chemical analysis and could see many differences even though their genetic data was same. It was thought that we have not biochemically profiled across the US or across major medical



facilities for some of these unexplained mystery illnesses or cancers. This data could be collected and then retroactively do biochemical analysis to use for sensor development.

- CDC does a NHNES=National Health and Nutritional Environmental Survey. This survey could provide some of this information.
- The data is available to all, but is not usable to most
- There are similarities between how you crowd source rare diseases and astronaut health

### Third discussion: Unique Aspects of Space Exploration (NIH and NASA)

The premise of this discussion was that space is the ultimate place to go study things but has numerous confounders. In cases, it isn't clear what researchers should be screening and most effects are multifactorial. Some exposures are additive compared to individual events and then have different durations. If all of the time points and dose responses are not available, how do we define it prospectively so we do this better in the future? For example, visual acuity problems have been happening all the time but we didn't know it. When it started to be investigated, it was realized that it had been attributed to other causes. We could have collected data and retrospectively analyzed it but did not.

- How do you know what to look for, what do you look for? NASA is tinkering around with handheld devices and small things, but if we figure out what to look for we could apply to Earth problems
- Example, CO2 sensors: In space, you get pockets of CO2 because air patterns are different in space. This concept could also be used for Earth-based situations.

### Wrap Up

In the next decade we will be at a point where we can look at everything and draw associations between things. We will get to a point where there are no confounders, but only signals. Knowing the value of each signal is the next step.

### **Breakout Session: FDA Guidelines on Mobile Health**

**Facilitator:** Megan Moynahan, Associate Director for Technology and Innovation (Acting), [FDA](#) Entrepreneurs in Residence Program

Summary: 15 participants

The breakout session began with a brief overview of the FDA and the facilitator asking what everyone's interests and/or burning questions for the FDA were as everyone went around the room to introduce themselves.

Megan has been with the FDA for 16 years where she spent most of her time reviewing medical devices. In the last 4 years she has worked in the Office of the Center Director working on

improving policy. Her main focus has been to shorten the time from concept to commercialization and reframing the business process. In April, the FDA launched the Innovation Pathway. This program was brought up in 6 months and held an innovation challenge for end stage renal disease. Currently there are 3 companies in the Innovation Pathway who are receiving coaching to get their devices to market quicker.

Summary of interests/burning questions:

- At what point in the development process should the FDA be contacted and who do you contact?
- Is there a process for “match-making” with external resources who actually work with the FDA?
- Would like to understand regulations in different countries with global health issues
- When is something considered a device and how do we navigate the FDA approval system?
- Where do you see things going in 5 years?
- Would like to know more about implementable guidelines
- What kind of review time can be expected from the FDA? 90 days? Two 45 day periods?
- Would like to understand guidelines for pilots and medications and medical devices they can use when flying since they have to be FDA approved
- Has the FDA considered coordinating efforts in mobile health somehow to give direction?
- For mobile health apps on the iPad, where is the FDA moving in the future?

First Discussion: How to interface with FDA

The field of mobile devices is growing rapidly and the FDA saw a lot of confusion in the market place when it came to understanding whether or not a device was regulated. As a result, the FDA attempted to create a guidance document that would do the following:

1. As mentioned, it is a growing field and the FDA wanted to show support toward the app industry and our changing lifestyles and behaviors. They also wanted to draw parity to things that were already regulated today.
2. Give assurance that when these technologies get used in an acute situation the data collected is correct and reliable if it is being used to do something that is a traditional medical device.
3. Example: blood glucose level measurement and trending. If you change your lifestyle, your glucose can change. If people are relying on app and it tells them to change insulin dosage without doctor approval or input - that's where we drew a line. The FDA wanted to focus on scaling back - enforcement digression. Not to impose requirements on these apps but reserve the right to change policy if needed.

Is my app a device?

There is a legal definition. The FDA has a small subset of oversight but in general health and wellness is the focus.

- If app has the same standard of care algorithm that is already accepted, why can it not be used? FDA: ex: glucose management software. If the app is just doing logging and tracking it is ok but if you are making decisions for the patient it becomes an issue.
- Where does FDA come in during the decision process? FDA: The regulatory piece doesn't prevent you from doing anything. It's more of have you managed risk enough to not hurt patients? The risk is different based on what the app does. It's all crunching data but the scope is different - from glucose measuring to surgery. FDA is taking a step back and proposing a different way of looking at this and answering these questions. Clinical support apps and at what level of care are being looked into. Scaling back and only focusing on high risks like death or delay in therapy apps. Things like what are the inputs to the tool? Where is it being used and how often it is being used? We are taking a step back and looking at the big picture. We are looking at areas where there is a potential to harm patients. Clarification - if an app has something that says to seek your doctor - FDA is not as concerned about it. If the app pings the doctor, than those are other ramifications.

There are a lot of people dancing on edges of “does it need FDA approval?” The FDA recommendation is to build it the way you want and come up with best product ever. You can interface with the FDA long before marketing approval is needed. We are always looking for things that challenge our policies so we can make them more transparent and easier to use. Challenge the group to think bigger so the FDA has to relook at practices.

- It would be useful to have some case studies available to compare or a collaborative work space so you don't have to go through FDA consultants who aren't in FDA anymore. Are these consultants slowing the process down?

How can FDA help people to self identify where you fit? What are those ideas?

- Creating an environment that is accessible with communication and direct understanding. Not having to wait 20-45 days to get an appointment to see the FDA. The FDA is working to supplement guidance with a website that is continuously updated and creating a FAQ repository. Our boundaries can't divulge IP but we can post examples of certain things that are being done for synergy purposes. There are also a lot of self training materials on how to get through the basics of the regulatory process. Are there better ideas?
- When mobile medical devices guidelines came out - we had comments. Intended use of a device in particular is an issue. When you think about the garage developers there is a need for more clarity of buzz terms. We also need to classify accessories or mention rules of these. Small business resources should be promoted instead of hidden. Also bring them into 21st century. Virtual tests on CDRH are available and will tell you if you understand the guidance or not.
- Medical devices for home use - nothing came out of it
- Innovation Pathway – the language mentioned that the focus should be on bigger public health issues than in smaller ones.

- Issue we are having with FAA - medical devices that transmit should be turned off during flight especially for 18 hour flights - FDA is looking into this. There is collaboration on this but not sure at what stage. We need to get together on medical issues.

Is part of the issue that FDA doesn't have enough people to process these requests - is that why it takes so long?

- The FDA is getting to a point where some of the money going toward medical devices will help us hire people for the upfront process.

We are moving into having consumers taking control of their health. Will this result in consumers having a lower tolerance for accuracy?

- Example: use of scales. Sometimes there is a 4-5 lb difference and medical decisions are being made on these facts. What are the different contexts and is there a way to generalize it? Transparency on FDA approval means the ability to engage back or provide feedback is also important. This lets you know you are thinking about them.

How many believe that everything FDA regulated is approved all the time?

- FDA doesn't look at everything - some things are self regulated by manufacturers. What is the decision point? When is something FDA regulated? It has to fit in a class 3 level device in how it's made, what it does, etc. This is a 3 tier system.
- There is no relation between drugs and medical devices but there are similar precautions for devices so they aren't completely different.

## Appendix D - Keynote: Todd Park, US Chief Technology Officer

Todd Park's keynote was more of a discussion than a formal address. This made his time with the NHHPC members and participants very interactive and dynamic. He started by thanking NASA and Kaiser Permanente for contributing to DC Health Data and Innovation Week. He then discussed the 3<sup>rd</sup> Health Datapalooza which was also held during DC Health Data and Innovation Week.

"It is a health data initiative, where the idea is to replicate what the government helped to trigger about 40 years ago when weather data was being released and used by the public. Now it is growing reservoirs of health related knowledge. This can be seen in the growing tide in healthcare apps and knowledge. The 1<sup>st</sup> gathering was 45 people, this week over 1600 people joined in over 2 days and 256 companies applied to be at the exhibit. Most of these companies were founded in last 6mo-1yr. Still trying to process how they can trigger the entrepreneurial system of NOAA. Face-to-face meetings are still amazing and we have learned over the last 2 years that is very true. Expertise in our society is more and more dispersed. If we could bring all the expertise together and do a people mash up – this would be huge and we would be connecting the brightest minds."

Todd then went on to ask the audience questions, stating "this group is a mash up too – and today you probably learned a lot at the workshop."

"What was most important brand new thing learned today?"

- Great interaction with FDA: great engagement
- Open mHealth: miniaturization of devices and being able to make sense of data, how do we take the devices and sensors for space exploration and make them actionable so astronauts can self diagnosis and treat themselves?
- NETRA: as great as this initiative is to exploit data, it is like reverse engineering, for him as an inventor. We need a hardware app store – it would be great to have access to what is out there, but we need to create a new system to invent new hardware.
  - Todd Park: he is all about the creation of new data and the ability to make it open, and the creation of new hardware—what is expected of new hardware that can advance innovation?
  - NETRA: his device gives Rx for eyeglasses and scans for cataracts—wants data from people who are completely healthy, not just people that are sick; also wants to congratulate FDA on their efforts
- Todd Park: apps are just the tip of the iceberg, also services, case management action, policy makers make better decisions if have data. Data as an agent of market

transparency—creates completion and produces value for everyone in the market place without having to use an iPhone specifically

- Imagine Kodak as an example applied to medical devices and hardware contributing to medical welfare. We should get really smart about hardware in addition to software and IT.
- If Todd Park wanted to talk to five people to get the best collective snapshot of status and trends in hardware, who would that be? Suggestions: Ramesh Raskar, Tim O'Reilly, Ray Kurzweil, Alex Glocum (?), Jose Marcus-Gomez (?)
- Todd gave out his email address, [Tpark@OSTP.eop.gov](mailto:Tpark@OSTP.eop.gov), and encouraged participants to send an email with further questions or suggestions.
- Todd: Not many hardware people came to Health Datapalooza
  - Hardware designer commented: there is not much interest because it is mostly about apps
- Participant: 90% of the data in the world has been created in the last two years, despite this, much of the data collected in the wellness space is not getting into the health space
  - Example: as hardware drops in cost, it is becoming ubiquitous and is throwing out all kinds of data, one example being running and fitness apps, and it is not clear that this is being used
- Participant: A friend is fighting a battle to get hold of his own data from a defibrillator company and he can't get it because the company says it is proprietary
  - Todd: that is what Blue Button is for - so you can get a copy of your own data, because it is your data, and if this is not a standard in the hardware world, it should be. The federal government is getting behind this effort so you can download something that says this data is mine and I can use it
    - This would fuel an enormous amount of data that could be used—so HHS should invest in hardware because hardware enables software!
    - Hardware data may not be usable, it can be messy, but one note to self: explicitly integrate hardware and software into next year's Datapalooza, and that we want blue button for hardware!
- Participant: there is software on a device, so the manufacturer doesn't want the data released to the patient, but will release it to the physician
  - Are we talking about releasing the data to the patient or supporting that doctor's obligation to give data to the person?
  - Todd: the first step in whatever form it is, is to distribute the data
- Blue Button is data from the past, whereas real-time measurement needs to be transposed

- The data is not structured, is messy, etc. but Blue Button said just put it out there—this evolved into enhancement of data, but that first step was crucial
  - So the question is should we pursue this? As hardware designers, we get all data, instead of saying hardware or software, just say “device.”
- Depends on the device if hardware and software are integrated or separate
  - For phones – they are separate
  - The reason patients cannot get their own data is not a technical issue, but is for business reasons
- Participant: from personal experience I’ve never had problem getting data, but I have had to ask for it.
- Participant: in an attempt to make a better 12 lead ECG, data is useless unless there are algorithms to translate it, but others would want raw data
  - There is always more data that can be mined.
- FDA: the other business reason manufacturers don’t want people to have data is because you can tell if/when the device is broken from the data
- FDA: seeing more and more devices with ways to get information, the first level is to get ports on devices. The answer to the liability question will come, but you have to figure out what do to with the zeros and ones and make sense out of the data, but you need to liberate it first.
- Todd: the X factor is patient intermediated health and patient exchange—we’re working on interoperability (is currently messy, unstructured) but give it to them anyhow until this is worked out. It is true that most people don’t want data, but if the sick do want it, give it to them—saying that they don’t know what to do with it is not an excuse not to give it to them if it isn’t costly. What would be the problem?
- Todd: A similar initiative is Green Button for cars. This is processed data not raw data, but the healthcare system was stymied for decades because they were obsessed with what would happen if you got your data, but Blue Button is saying I don’t know what is going to happen, but U.S. official government policy is that people should have access to their own health data.
- Participant: everything today is a system of systems; if you want to keep all that raw data it would take the room to fill it. What is the context? What is going to be done with it?
- Hardware designer: he wanted his father’s heart rate variability data to correlate with stress to make him more comfortable. He wanted to give the data to friends who could do something with it—this is not a matter of what someone thinks can be done with it or not, it is a matter of what you want to do with it. Let people have it—if they can’t afford the storage, that’s not your problem.
- Individuals have a right to it, doesn’t mean they’re going to ask for it.

- Tim O'Reilly told Todd when they began to liberate data, they engaged developers from the beginning to find out how to use it so they understood the broad potential. The data can then go to more entrepreneurs interested in the data.
- What people have done with data, no one 10 or 50 years ago would have even dreamed of, but there is a bunch of other people who might know what to do with it. But if they don't get it, they can't figure it out.
- We are releasing unstructured data and people are structuring it in different ways. 95% of those entrants involved who could take HHS data didn't even know what HHS did and didn't know that it had all of this data and that they could get it for free.
- National Library of Medicine: The NLM focuses on standardizing data. They knew decades ago eventually someone could handle the data, and so they kept it out there and decades later it could be used. If they had been tracking ones and zeros for visual acuity in astronauts from the start, they could now go back and work with it and look for what we did not know we wanted.
- The state of Maryland prohibits genetic testing
  - Knowledge of individual death or disability changes the way they purchase insurance so people cannot have more information than insurers.



## Appendix E – NHHPC Workshop Participating Organizations (47)

The Advisory Board Company
American Association of Colleges of Pharmacy
Astronauts4Hire
AyDeeKay
Be Well
Biomatrica
Center for Health, Culture and Society
DNA Medicine Institute
CooperSoft
FAA Civil Aerospace Medical Institute
FDA
Futron
Health and Human Services (HHS)
IBM
Idiopathic Intracranial Hypertension – United Kingdom
iMedicalApps.com
Johnson & Johnson
Kaiser Permanente
MEDgle
MIT Media Lab
National Institute of Health
National Library of Medicine
NASA/NESC
NASA
NASA Johnson Space Center
NASA Langley Research Center

National Space Biomedical Research Institute (NSBRI)
NYU School of Medicine
Open mHealth
PepsiCo
Philips
RxmindMe
Qualcomm, Inc.
SolaMed Solutions, LLC
SpaceRef Interactive
The National Center for Human Performance/Texas Medical Center
United States General Services Administration (GSA)
University of California San Francisco School of Medicine
Vital Space Inc, Scripps Translational Science Institute
WebFirst, Inc
West Health Policy Center
West Wireless Health Institute
Woodrow Wilson International Center for Scholars
Wyle
Yet2.com
Zansors, LLC